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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,325	02/16/2006	Shailesh Bhamare	SMC-PT004	2977

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EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
08/06/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,325	BHAMARE ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 6, 8 - 11, 13, 14, 16, 17, 19 - 26, 28, 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 - 6, 8 - 11, 13, 14, 16, 17, 19 - 26, 28, 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed May 21, 2008, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application. Claims 7, 30 and 31 have been cancelled in the amendments filed on May 21, 2008.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1 – 3, 5 – 9, 16, 17 and 21 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 30, 37, 39 and 40 of copending Application No. 10/495,961. Due to the amendments to the claims, this provisional rejection is now applied to claims 1 – 3, 5 – 6, 8, 9, 16, 17 and 21 of the instant application.

Applicant traverses this rejection on the grounds that the copending application lists the use of selective hydrophilic polymer matrix, essentially sodium alginate, xanthan gum and a calcium salt, and that the parent PCT application states that carbomers as recited in the instant application are different than polymers like xanthan gum. The claimed invention in the co-pending application leads to improved stability while the carbomers are used to control the release of the cephalosporin antibiotic. The recited function of calcium ingredient in the two applications is different. Further, neither

application has issued and the claims of each application are not in their final form and the Applicant intends to amend the claims of '961.

These arguments are not found to be persuasive. The independent claim of '961, in the amendment to '961 filed June 27, 2008, recites "one or more hydrophilic polymers comprising a sodium alginate, a xanthan gum or a mixture thereof". "Hydrophilic polymers" encompass the carbomer polymers of the instant claims and the open language of comprising is used in both the preamble and in conjunction with the hydrophilic polymer, so the presence of carbomers in the compositions claims of '961 is not excluded. The claims are drawn to compositions, and the specific label (such as lubricant or stabilizer) attached to a particular ingredient in one application versus another does not lend patentably distinction, as the same compound can have many different labels applied to it.

Therefore, this provisional rejection is MAINTAINED.

3. Claims 1, 2, 9, 10, 12, 14, 16, 17, 21 and 28 – 30 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6, 10 – 15 and 17 – 19 of copending Application No. 11/579,988. This rejection is WITHDRAWN.

Claim Rejections - 35 USC § 112 – 2nd Paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 6 and 8 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because the required ingredients that were only identified by their tradenames. In response, applicant's have amended the claims from CARBOPOL 971P® and CARBOPOL 974P® to carbomer 971P and carbomer 974P. This amendment does not completely resolve the issue as the numbers related to different trademarked products with different properties. Determination of the properties of the polymer (monomers, amount of cross-linking, viscosity, etc.) being claimed still relies upon a part of the trademarked names. As such, this rejection is MAINTAINED.

6. Claims 10, 13 and 17 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because "and the like" was included in the claims. The amendments have resolved this problem so this rejection is WITHDRAWN.

7. The rejection of claims 30 and 31 under 35 U.S.C. 112, second paragraph, is moot as these claims have been amended.

8. Claim 25 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because of the "substantially the same". Applicant

was correct in that a typographical error was made and that rejection is in reference to claim 22, the only pending claim which contains the phrase identified as indefinite.

Applicants traverse the rejection of claim 22 by reference to a portion of the specification shown below:

> The T > MIC at 0.25 mcg/ml was achieved for about 75% of the dosing interval and T > MIC of 2 mcg/ml was achieved for almost 49% of the dosing interval. Both these values are for a time period of more than the 40% of the dosing interval required indicating that it is an excellent controlled release formulation, which not only achieves the desired pharmacodynamic parameters but also manages to maintain the Cmax values **substantially similar** to those obtained for immediate release formulations. In fact, the Cmax values were within the 80-120% confidence interval recommended by the US FDA.

However, this section does not define substantially similar as the 80 – 120% confidence interval recommended by the US FDA. It appears that the values obtained and labeled as substantially similar were inside this range and that, for example, a Cmax value with a 80% confidence interval could be within the interval recommended by the FDA but would not be considered “substantially similar”. Also, the claim itself recites "substantially the same” and not “substantially similar”, and “substantially the same” could imply a closer correspondence being required than “substantially similar”.

Therefore, the rejection of claim 22 for the relative term “substantially the same as” is MAINTAINED.

New Claim Rejections - 35 USC § 112 – 2nd Paragraph

9. Claims 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim depends from cancelled claim 7. As this claim previously depended from claim 6, and cancelled claim 7 contained the limitations incorporated into the independent claim, for the purposes of applying art, claim 8 has been interpreted as being dependent from claim 6.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1 – 11, 13, 14, 16, 17, 19 – 26 and 28 – 31 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kshirsagar et al. (WO 04/019901). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed February 21, 2008 and those set forth below. Due to the amendments to the claims, this rejection is now applied to claims 1 – 6, 8 – 11, 13, 14, 16, 17, 19 – 26 and 28.

Applicant traverses this rejection on the ground that the claims of Kshirsagar et al. clearly relate to the use of a combination of polymers for preparing controlled release with entirely different polymers than those of the present invention. Claim 24 of the instant application recites carbomer with specific properties and the Kshirsagar would not teach one of ordinary skill that different grades of carbomers could be combined for controlled release in the recited ranges or with the recited properties. Additionally, Kshirsagar does not teach that at least two carbomers could be used as essential components for controlled release.

These arguments are not found to be persuasive. The disclosure of Kshirsagar is not limited to the claims and the use of carbomers is disclosed in the document. As cited, a mixture of various carbopols as potential ingredients in the composition is disclosed (p 16, ln 25 – 28). Kshirsagar does not describe the quantity of these ingredient(s) using the word "minute". In fact, in example 4 (p 20), CARBOPOL® 971P is present in the composition is amount of 1.06% by weight, an amount encompassed by the range recited in independent claim 1 of the instant application. The amount of the excipients and polymers presence in a controlled release composition are result effective parameters that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results.

Contrary to Applicants assertion, claim 24 does not require a carbomer with certain properties, but rather a composition with certain physical properties (release rates) of the dosage form and only specifies a "release-controlling polymer". While certain combinations of certain amounts of carbomers can be used to achieve this release profile, the release profile can also be obtained using other controlled release polymers. The language of the claims of the instant application is open so other ingredients besides the at least two carbomers can be present in the composition. Appreciation of the properties of a substance, in this case the in addition to carbomers being added to enhance the integrity of the composition, carbomers can also alter the

release rate of the active ingredient, both properties being inherent to the carbomer itself, does not necessarily make the claim patentable. Therefore, the rejection of these claims over Kshirsagar is MAINTAINED.

14. Claims 1 – 9, 13, 14, 16, 17, 19 – 26 and 29 – 31 were rejected under 35 U.S.C. 103(a) as being unpatentable over Katzhendler et al. (US 6,399,086) in view of Mayron (US 3,074,8562). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed February 21, 2008 and those set forth below. Due to the amendments to the claims, this rejection is now applied to claims 1 – 6, 8, 9, 13, 14, 16, 17, 19 – 26 and 28.

Applicant traverses this rejection on the ground that Katzhendler et al. discloses a very specific release profile of beta lactam antibiotics with a burst effect followed by controlled release that is achieved by free drug to provide the burst and granules or another layer with a polymer and antibiotic to provide the controlled release. Katzhendler et al. teaches a completely different mechanism of drug release and does not teach the use of carbomers as suitable as a delayed release polymer. Example 5 of Mayron, the secondary reference, refers “the carboxy vinyl polymer”, and thus does not teach compositions with more than one polymer. The CARBOPOL® 934 used in this example is not suitable for release of cephalosporins to a portion of the gastrointestinal tract where cephalosporins are preferably absorbed and that CARBOPOL® 934 is not suitable. Additionally, the ratio of drug to polymer of at least 1:0.5 taught by Mayron is not applicable to the present invention where the drug to polymer ratio is 1:0.35.

These arguments are not found to be persuasive. While example 5 of Katzhendler et al. uses only one CARBOPOL® polymer, the example cited in the previous office action (example 2; col 4, ln 12 – 24) uses a mixture of CARBOPOL® 940 and CARBOPOL® 941. Therefore, Katzhendler et al. does disclose the use of more than one carbomer in a single composition. The open language of the claims means that the presence of a burst release is not excluded from the claims of the instant application and as the ingredients of the composition meet the limitations recited in the claims, these claims are rendered obvious by the combined teachings of Katzhendler et al. and Mayron.

With the exception of claims 6 and 8, the pending claims of the instant application do not exclude certain carbomers from the claimed composition. The ratio of drug to polymer is not recited in the rejected claims. Only claim 26 recites amounts in weight percent for both the drug and the polymer, and as ranges are put forth, a variety of drug to polymer ratios are being described. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore, this rejection is MAINTAINED.

15. Claims 1, 10 11 and 28 were rejected under 35 U.S.C. 103(a) as being unpatentable Katzhendler et al. (US 6,399,086) in view of Mayron (US 3,074,8562) in further view of Patel et al. (US 6,248,363). This rejection is MAINTAINED for the

reasons of record set forth in the Office Action mailed February 21, 2008 and those set forth below.

Applicant traverses this rejection on the basis that the disclosure of Patel et al. does not overcome the deficiencies of Katzhendler et al. and Mayron as to the teachings of more than one carbomer.

As discussed in greater detail above, Katzenhendler et al. and Mayron does teach a composition comprising at least carbomers. Therefore, this rejection is MAINTAINED.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW